West Virginia Medical Cannabis Advisory Board Report and Recommendations



Rahul Gupta, MD, MPH, MBA, FACP
Commissioner and State Health Officer
Bureau for Public Health
West Virginia Department of Health and Human Resources
Medical Cannabis Advisory Board Chairman

February 21, 2018



TABLE OF CONTENTS

Members of the Advisory Board	3
Executive Summary of Board Recommendations	4
Introduction	5
Advisory Board Recommendations	5
Work Group 1	6
Work Group 2	7
Work Group 3	7

MEMBERS OF THE ADVISORY BOARD

- Rahul Gupta, MD, MPH, MBA, FACP, Chair
- Arvinder Bir, MD, Huntington
- Colonel Jan Cahill, Superintendent, West Virginia State Police, South Charleston
- Michael "Joe" Deegan, Social Worker, Cross Lanes
- Michelle R. Easton, PharmD, Charleston
- James Felsen, MD, Great Cacapon
- W. Jesse Forbes, Esquire, Charleston
- Joseph Hatton, Horticulturalist, West Virginia Department of Agriculture, Charleston
- Kimberly Knuckles, Pharmacist, Beaver
- Rudy Malayil, MD, Huntington
- D. Keith Randolph, Prosecuting Attorney, Madison
- Joseph Selby, MD, Morgantown
- · Russell A. Williams, Patient Advocate, Nitro

EXECUTIVE SUMMARY OF BOARD RECOMMENDATIONS

The West Virginia Medical Cannabis Advisory Board met on Tuesday, February 20, 2018, and approved the following recommendations for consideration by the Governor and West Virginia Legislature during its 2018 Legislative Session.

Recommendation 1.1

Amend the Act to clarify the requirements and responsibilities for physicians who issue certifications to patients to include:

- A determination by the practitioner that a patient has no past or current medical condition(s) or medication use that would constitute a contraindication for the use of cannabis.
- b) A determination by the practitioner that a patient is experiencing serious pathophysiological discomfort, disability or dysfunction that may be attributable to a serious medical condition(s) and possibly benefit from cannabis treatment when current medical research exhibits a moderate or higher probability of efficacy.
- c) That the practitioner has educated the patient about cannabis and its safe use.

Also, to include a statement by the practitioner attesting that he/she has performed these requirements on a form determined by the West Virginia Department of Health and Human Resources, Bureau for Public Health.

Recommendation 1.2

Replace the phrase "Serious Medical Conditions" with the phrase "Medical Conditions with Possible Serious Manifestations" throughout.

Recommendation 2.1

Include dry leaf or plant form of medical cannabis medically appropriate for administration by vaporization or nebulization.

Recommendation 3.1

Remove limitations on the number of permits the Bureau for Public Health may issue for growers, processors, and dispensaries.

Recommendation 3.2

Remove the limitation that a grower or processor may not also be a dispensary to permit the vertical integration of growers, processors and dispensaries.

Recommendation 3.3

The Legislature should evaluate the need for the requirement that a physician or pharmacist must be onsite at all times during the hours the dispensary is open to receive patients and caregivers.

Recommendation 3.4

Authorize a pre-registration process for potential medical cannabis patients to more clearly ascertain the market interest within West Virginia for medical cannabis.

INTRODUCTION

This report represents the first report of the West Virginia Medical Cannabis Advisory Board after its establishment pursuant to the passage of Senate Bill No. 386, The Medical Cannabis Act, (Act) in 2017. Under the Act, the board has the following duties:

- 1) Examine and analyze the statutory and regulatory law relating to medical cannabis within this state.
- 2) Examine and analyze the law and events in other states and the nation with respect to medical cannabis.
- Accept and review written comments from individuals and organizations about medical cannabis.
- 4) Issue a written report to the Governor, the Senate and the House of Delegates that includes recommendations on:
 - a) Whether there should be changes to the types of medical professionals who can issue certifications to patients.
 - b) Whether to change, add or reduce the types of medical conditions which qualify as serious medical conditions.
 - c) Whether to change the form of medical cannabis permitted.
 - d) Whether to change, add or reduce the number of growers, processors or dispensaries.
 - e) How to ensure affordable patient access to medical cannabis.
 - f) Whether to permit medical cannabis to be dispensed in dry leaf or plant form, for administration by vaporization.

The first meeting of the board commenced on August 16, 2017. Four subsequent board meetings were held, one taking place in Morgantown and the remainder in Charleston. Public comment was accepted at all board meetings. The board established three work groups to provide focused recommendations that may then be approved by the board for submission to the West Virginia Legislature. The following recommendations represent each work group and its charge.

ADVISORY BOARD RECOMMENDATIONS

The board has been charged by the Act with making recommendations related to five specific areas concerning medical cannabis. Recommendations are submitted within

this report to the Legislature in order to achieve the tasks set out through passage of the Act.

Since its original appointment in 2017, the Commission has met on five occasions; three times in 2017 and twice in 2018. The work groups created in 2017 continue to meet in 2018 to take on the tasks as outlined in the Act.

The following is a compilation of the recommendations organized by the respective work groups and their assigned task. The recommendations have been approved by the full board and are being advanced as recommendations of the full Medical Cannabis Advisory Board.

Work Group 1

Charge: Assess and make recommendations to change, add, or reduce the types of medical conditions that qualify as serious medical conditions under the Act and the types of medical professionals that can issue certifications to patients.

Membership: James Felsen, MD – Chair; Arvinder Bir, MD; Rudy Malayil, MD; and Kimberly Knuckles.

Recommendations:

Recommendation 1.1

Amend the Act to clarify the requirements and responsibilities for physicians who issue certifications to patients to include:

- A determination by the practitioner that a patient has no past or current medical condition(s) or medication use that would constitute a contraindication for the use of cannabis.
- b) A determination by the practitioner that a patient is experiencing serious pathophysiological discomfort, disability or dysfunction that may be attributable to a serious medical condition(s) and possibly benefit from cannabis treatment when current medical research exhibits a moderate or higher probability of efficacy.
- c) That the practitioner has educated the patient about cannabis and its safe use.

And to include a statement by the practitioner attesting that he/she has performed these requirements on a form determined by the Bureau for Public Health.

Recommendation 1.2

Replace the phrase "Serious Medical Conditions" with the phrase "Medical Conditions with Possible Serious Manifestations" throughout.

Work Group 2

Charge: Assess and make recommendations as to the forms of medical cannabis that can be permitted under this Act, including whether dry leaf or the plant form of cannabis should be dispensed for administration by vaporization.

Membership: Michelle Easton, PharmD – Chair; Joseph Selby, MD; D. Keith Randolph, Esg.; and Russell Williams.

Recommendations:

Recommendation 2.1

Include dry leaf or plant form of medical cannabis medically appropriate for administration by vaporization or nebulization.

Work Group 3

Charge: Assess and develop recommendations as to how to ensure affordable patient access to medical cannabis and whether to change, add or reduce the number of growers, processors, or dispensaries.

Membership: W. Jesse Forbes, Esq. – Chair; Col. Jan Cahill; Joseph Hatton; and Joe Deegan.

Recommendations:

Recommendation 3.1

Remove limitations on the number of permits the Bureau for Public Health may issue for growers, processors and dispensaries.

Narrative

The Advisory Board and work group continue to examine other states' experiences and gather information. The work group is not currently in a position to recommend a specific number for the increase but work group members believe the current numbers are likely too low to provide for adequate patient access and market viability in light of the survey results and interest level that has been indicated thus far in the Advisory Board's tenure. Further, by increasing the number of permits available, a broader cross-section of interested businesses would be able to take part in the process allowing for an increase in affordable patient access to medical cannabis.

Recommendation 3.2

Remove the limitation that a grower or processor may not also be a dispensary to permit the vertical integration of growers, processors and dispensaries.

Narrative

In researching this issue, it appears West Virginia is an outlier in prohibiting vertical integration among the 29 states that have approved medical cannabis laws. In

presentations to the full Advisory Board, as well as reviews of applicable tax codes, it seems that the three-tiered system currently provided in the law would make it less economically viable for entities to enter into this market and to provide an affordable product for patients.

Recommendation 3.3

The Legislature evaluate the requirement that a physician or pharmacist must be onsite at all times during the hours the dispensary is open to receive patients and caregivers.

Narrative

In reviewing the current law, it is unclear what role a physician or pharmacist would bring to the dispensary process. The current law states that physicians and pharmacists cannot prescribe medical cannabis. Further, the code specifically states that physicians and pharmacists cannot "otherwise treat" patients at the dispensaries. Having a physician or pharmacist onsite at each dispensary during operations would dramatically increase the dispensary's operating costs, increasing the costs to patients for the product. However, if physicians and pharmacists are not present to treat patients at the dispensaries, it is unclear what service their required presence would provide. In fact, if not providing treatment, it may not be possible for a physician or pharmacist to even access any patient data during the dispensing process. Therefore, the work group recommends that the role of physicians or pharmacists being required at a dispensary be reevaluated and that their involvement in that process be more clearly defined to ensure the necessity to increase costs by requiring their presence be justified. This recommendation is made to ensure affordable patient access to medical cannabis.

Recommendation 3.4

Authorize a pre-registration process for potential medical cannabis patients to more clearly ascertain the market interest within West Virginia for medical cannabis.

Narrative

The work group believes that such a process would allow for a better and more exact figure of the potential market so that this board and the Office of Medical Cannabis are able to determine what numbers and geographic regions of license holders would best serve the patients. Further, such a process would allow for a better understanding of the potential market for anyone wishing to open businesses to support this industry. The work group recommends that a nominal fee be established for potential patients to preregister with the revenue from such fees going to the Office of Medical Cannabis to support the pre-registration process and otherwise to fund the start-up costs associated with implementing the medical cannabis laws in West Virginia. By ascertaining more specific numbers and data regarding patients willing to sign up and pre-register, there will be a better understanding of the potential market in West Virginia which will be beneficial in establishing standards for affordable patient access and the number of permits necessary.